

0547 '02 JAN -9 112 104

January 2, 2002

**SUITABILITY PETITION**

Dockets Management Branch  
Food and Drug Administration (HFA-305)  
12420 Parklawn Drive (Room 1-23)  
Rockville, MD 20857

RE: Suitability Petition  
Docket Number 01P-0504/CP1

Dear Sir/Madam:

The above referenced petition was a request to the Food and Drug Administration to permit filing of an abbreviated new drug application for a tableted product containing 10 mg hydrocodone bitartrate/400 mg acetaminophen and 7.5 mg hydrocodone bitartrate/400 mg acetaminophen. This petition was filed by our firm on behalf of the petitioner ANDAFAB ONE LP, Grand Prairie, TX 75050.

We have been informed by the agency that these strengths are now published in, "Approved Drug Products with Therapeutic Equivalence Evaluations" (The Orange Book), under ANDA 40288 issued to Endo Pharmaceuticals. Therefore, since these strengths are now a Referenced Listed Drug (RLD), no suitability petition is required. On that basis we hereby request the agency to withdraw the above referenced petition without prejudice.

If you have any questions on this, please do not hesitate to contact me.

Sincerely,



Paul W. Carr, P.E., R.A.C.  
Regulatory Consultant

PWC:pbh

cc: Ms. Darlene M. Ryan  
Manager  
ANDAFAB ONE LP

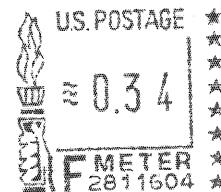
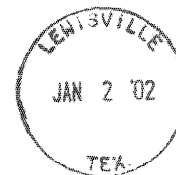
FAX: Mr. Martin H. Shimer (301-594-1174)

01P-0504

WDL1

**SHOTWELL CARR & CHRISTENSEN**

3535 FIREWHEEL DRIVE, SUITE A  
FLOWER MOUND, TEXAS 75028-2628



Documents Management Branch  
Food and Drug Administration (HFA-305)  
12420 Parklawn Drive (Room 1-23)  
Rockville, MD 20857

